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Comparing the Performance of Quantitative Cytology versus the Oral CDX Brush Test®.

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Introduction: Analysis of cytological samples from potentially malignant oral lesions (PMOLs) can be of diagnostic and possibly prognostic value to the clinician. **Objective:** To compare the performance, on cytological samples procured from subjects with known SCCA or PMOLs, of quantitative cytology (Perceptronix, Canada) versus the Oral CDX Brush Test® (CDX, USA) against matched histopathology ("gold standard"). **Methods:** Subjects with known SCCA or PMOLs (categorized into low or high risk of clinical suspicion) underwent an oral brush biopsy, whereupon a cytological sample was plated and fixed. Instead of discarding the brushes, the tips with residual cells were retained and fixed. Unless a known SCCA, a scalpel biopsy was immediately performed at the brush site and tissue sent for histopathology. Glass slides were sent to CDX for modified Papanicolau staining and automated cytological analysis, and reported by a cytopathologist as normal (CDX negative) or abnormal (CDX positive or atypical). Leftover brushes were sent to Perceptronix, cytospun, underwent Feulgen-Thionin staining, and DNA ploidy analysis using the ClearCyte™ automated image cytometry system. Galleries containing nuclei with non-diploid DNA content were reviewed by a cytopathologist, and reported as normal or abnormal. **Results:** A total of 86 cytological samples were of sufficient yield to undergo both tests. Of these samples, 57 (66%) had a diagnosis of dysplasia or SCCA. Compared to the "gold standard", the sensitivity/specificity/PPV/NPV of quantitative cytology versus the Brush Test® in detecting dysplasia (any grade) or SCCA were 61/100/100/57% versus 77/83/90/65% respectively. Overall performance increased on high risk suspicion PMOLs and when detecting higher grade dysplasias or SCCA. Quantitative cytology had additional value in resolving CDX atypical results. **Conclusion:** Each test offers an advantage and disadvantage over the other. Longitudinal studies are needed to assess the utility of such tests in low risk PMOLs or low grade dysplasias.

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